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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,583	06/08/2000	Tony N. Frudakis	210121.419C9	1221

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EXAMINER
SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/09/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/590,583	Applicant(s) FRUDAKIS ET AL.	
	Examiner Alexander H. Spiegler	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-57 and 60* is/are pending in the application.

4a) Of the above claim(s) *1-3,8-15 and 17-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6,16 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to Paper No. 20, filed on January 15, 2003. Currently, claims 1-6, 8-57 and 60 are pending; Claims 4-6, 16 and 60 have been examined on the merits, and claims 1-3, 8-15, and 17-57 have been withdrawn from consideration. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 60 is indefinite over "a detection reagent" for use in a polymerase chain reaction or hybridization assay because it is not clear as to what is considered to be "a detection reagent" for use in a polymerase chain reaction or hybridization assay. Does this mean a fluorescent label, a probe, luciferase? The metes and bounds of "detection reagent" are unclear.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 4-6, 16 and 60 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Applicants are directed to MPEP § 2107, which states that when determining the utility of an application, the Examiner must, "**review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible**".

In the instant case, Applicants do not assert a specific and substantial utility that is credible or a well-established utility for SEQ ID NO: 307 or fragments thereof.

The specification contains over 200 nucleic acid sequences (pg. 9, ln. 13-15), which Applicants claim have the following, alleged utilities:

- "the polynucleotide sequences provided herein can be advantageously used as probes or primers for nucleic acid hybridization" (pg. 14, ln. 24-26)...Polynucleotide primers and probes may be used to detect the level of mRNA encoding a tumor protein, which is also indicative of the presence or absence of a cancer. In general, a breast tumor sequence should be present at a level that is at least three fold higher in tumor tissue than normal tissue" (pg. 91, ln. 9-12);

- "the present invention concerns formulation of one or more of the polynucleotide compositions for administration to a cell or an animal, either alone, or in combination with one or more other modalities of therapy " (pg. 71, ln. 4-7);

These alleged utilities summarized above are neither substantial nor specific, since they are generic in nature and applicable to a myriad of such compounds (e.g. nucleic acids). Probes and primers can be designed from **any** polynucleotide sequence, as well as, the fact that polynucleotides can be formulated to be compositions for administration to a cell or an animal, either alone, or in combination with one or more other modalities of therapy. While these

utilities are credible, they are not specific or substantial, since the specification does not disclose nucleic acid target. Since these asserted utilities are not present in mature form (i.e. no specific target), they could not be readily used in a "real world" sense", and thus, not substantial.

The specification teaches that a full-length cDNA (SEQ ID NO: 307) and its corresponding amino acid sequence (SEQ ID NO: 308) were obtained (pg. 103, ln. 23-24). However, the specification does not teach any significant or functional characteristics of the polynucleotide or its corresponding amino acid. Furthermore, the specification does not teach a well-established utility for the claimed polynucleotide.

MPEP § 2107 additionally states:

"The 35 U.S.C. 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:
(i) Explicitly identify a specific and substantial utility for the claimed invention; and
(ii) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well established **at the time of filing**".

In the instant case, Applicants have not "explicitly identif[ied] a specific and substantial utility for the claimed invention". Furthermore, the specification has not provided any evidence that "one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established **at the time of filing**".

If Applicants traverse this rejection, Applicants should explicitly identify a specific, substantial, and credible utility or a well-established utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

6. Claims 4-6, 16 and 60 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible

utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Response to Applicants Arguments

In order for a polynucleotide encoding a polypeptide to be useful for detection or diagnosis of a disease or disorder, there must be a well established or disclosed correlation or relationship between the encoded polypeptide and the disease or disorder. The presence of a polypeptide in tissue (or the isolation of a polynucleotide) that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease *in the absence of some information regarding a correlative or causal relationship between the expression of the claimed polynucleotide and the disease.* If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polypeptide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide encoding a polypeptide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide encoding a polypeptide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Applicants argue that the claimed polynucleotide is useful for detection (i.e. diagnosis) of breast cancer; however, the only evidence that is provided is that the claimed polynucleotide was isolated from breast tumor tissue. The specification has failed to teach any evidence regarding the expression of the claimed polynucleotide and breast cancer. Thus, there is no correlation that the claimed invention can be used for detection of breast cancer. For example, if the specification demonstrated that the claimed polynucleotide was overexpressed in tumor tissues, and not expressed in normal tissues, Applicants invention would be specific, substantial and credible under U.S.C. 101. However, the specification lacks such a teaching. Accordingly, the rejection is maintained.

Conclusion

7. No claims are allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
April 4, 2003

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
4/7/03